IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION

MELANIE STACEL, Plaintiff, v. TEVA PHARMACEUTICALS USA, INC. Defendant.	Case No. 08-CV-1143 Judge Joan B. Gottschall Magistrate Judge Jeffrey Cole

ANSWER OF DEFENDANT TEVA PHARMACEUTICALS USA, INC.
TO PLAINTIFF'S FIRST AMENDED COMPLAINT

Defendant Teva Pharmaceuticals USA, Inc. ("Teva"), by its attorneys, Eimer Stahl Klevorn & Solberg LLP and Goodwin Procter LLP, as for its Answer to the First Amended Complaint filed on February 28, 2008 ("Amended Complaint"), states the following:

JURISDICTION

1. Plaintiff is an adult citizen and resident of the State of Illinois.

ANSWER: Teva denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 1 of the Amended Complaint.

2. Defendant Teva Pharmaceuticals USA, Inc., hereinafter referred to as "Teva Pharmaceuticals," is a corporation which is incorporated in the State of Delaware and has its principal place of business in North America, and at all time relevant to the allegations contained herein was engaged in the business of testing, designing, manufacturing and selling a drugs [sic] commonly known as minocycline and/or minocycline-containing products, hereinafter referred to as "minocycline products."

ANSWER: Teva admits that it is a corporation organized and existing under the laws of the State of Delaware and having its principal place of business in North America. Teva further admits that from time to time it has manufactured and sold minocycline.

3. Plaintiff diagnosed [sic] with injury on August 25, 2005, and this complaint is properly brought within the applicable statute of limitations.

ANSWER: Teva denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 3 of the Amended Complaint, and respectfully refers all conclusions of law to the Court.

4. Jurisdiction is based on diversity of citizenship of the parties hereto under Title 28, United States Code, §1332.

ANSWER: Teva respectfully refers all conclusions of law to the Court.

5. The amount in controversy exceeds the sum of Seventy-Five Thousand Dollars ($75,000), exclusive of interest and costs.

ANSWER: Teva denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 5 of the Amended Complaint, but admits that Plaintiff alleges the amount in controversy exceeds $75,000.

6. Venue is proper pursuant to Title 28, United States Code, §1391.

ANSWER: Teva respectfully refers all conclusions of law to the Court.

7. Plaintiff was prescribed the drug minocycline for treatment of acute acne beginning July 9, 2004 in a 100 mg/day dosage.

ANSWER: Teva denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 7 of the Amended Complaint

8. As part of her treatment, from July 2004 forward, Plaintiff regularly took prescription minocycline for acute acne.

ANSWER: Teva denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 8 of the Amended Complaint.

9. Plaintiff purchased and consumed minocycline products which were sold, manufactured, distributed, packaged, or otherwise placed into commerce in the State of Illinois by defendant Teva Pharmaceuticals.

ANSWER: Teva denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 9 of the Amended Complaint.

10. Plaintiff was ignorant of the dangerous nature of minocycline and of the nature of the risks incurred by ingesting minocycline-containing products, including developing drug-induced lupus.

ANSWER: Teva denies knowledge or information sufficient to form a belief as to the state of Plaintiff's knowledge as alleged in paragraph 10 of the Amended Complaint, and denies that minocycline has a dangerous nature.

11. While taking minocycline, plaintiff got the disease commonly known as lupus.

ANSWER: Teva denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 11 of the Amended Complaint.

12. Plaintiff began taking minocycline in approximately July 2004. Subsequently, Plaintiff was diagnosed with drug-induced lupus in September of 2005.

ANSWER: Teva denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 12 of the Amended Complaint.

13. As a direct and proximate result of the wrongful acts and/or omissions of Defendant, Plaintiff developed and was diagnosed as having drug-induced lupus.

ANSWER: Teva denies each and every allegation contained in paragraph 13 of the Amended Complaint.

14. Plaintiff would not have ingested minocycline as described herein, or would have discontinued use, or would have used safer alternative methods, had Defendant disclosed the true health consequences, risks, and adverse events, including the increased incidence and risk of drug-induced lupus and other illnesses, caused by their drug.

ANSWER: Teva denies knowledge or information sufficient to form a belief as to Plaintiff's conduct as alleged in paragraph 14 of the Amended Complaint, and denies each and every allegation relating to minocycline.

15. Plaintiff has suffered great pain, physical impairment, mental pain and anguish, losses to her personal property and possessions, and fear of death.

ANSWER: Teva denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 15 of the Amended Complaint.

COUNT I
PRODUCTS LIABILITY – NEGLIGENCE

16. Plaintiff reasserts and re-alleges the above general allegations with respect to this claim.

ANSWER: Teva incorporates by reference paragraphs 1 through 15 of this Answer as if fully set forth at length herein.

17. It was reasonably foreseeable by Defendant Teva Pharmaceuticals that Plaintiff and other consumers would be ingesting Defendant's minocycline products.

ANSWER: Teva denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 17 of the Amended Complaint, except admits that from time to time Teva has manufactured and sold minocycline.

18. Defendant Teva Pharmaceuticals participated in, authorized and directed the production and promotion of minocycline products when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of minocycline.

ANSWER: Teva denies each and every allegation contained in paragraph 18 of the Amended Complaint, and specifically avers that Teva complied at all times with applicable statutory and regulatory requirements and obligations with respect to its minocycline product.

19. Defendant Teva Pharmaceuticals had a duty to exercise reasonable care for the safety of Plaintiff and others who were using Defendant's minocycline products.

ANSWER: Teva respectfully refers all conclusions of law to the Court.

20. Prior to, during, and after the time Defendant Teva Pharmaceuticals manufactured, produced, processed, packaged, designed, distributed, and/or shipped the minocycline products to which Plaintiff digested, Defendant knew, or in the exercise of ordinary or reasonable care ought to have known, that consumption of their minocycline products caused disease and/or death.

ANSWER: Teva denies each and every allegation contained in paragraph 20 of the Amended Complaint.

21. Notwithstanding the aforementioned duty, Defendant Teva Pharmaceuticals was negligent by one or more of the following acts or omissions in that Defendant:

a. Failed to adequately warn Plaintiff and/or others of the health hazards concerned with ingestion of minocycline;
b. Failed to recommend and/or provide proper cautions and warnings, to ensure Plaintiffs and/or other's safety;
c. Failed to warn Plaintiff and/or others of the danger and harm from consumption of minocycline;
d. Failed to instruct Plaintiff or others in the use of precautionary measures in relation to minocycline

ANSWER: Teva denies each and every allegation contained in paragraph 21 of the Amended Complaint, and respectfully refers the Court to the appropriate product labeling for the terms thereof.

22. As a direct and proximate result of the acts and omissions of the Defendant Teva Pharmaceuticals, Plaintiff was injured as described above.

ANSWER: Teva denies each and every allegation contained in paragraph 22 of the Amended Complaint.

COUNT II
BREACH OF EXPRESS AND IMPLIED WARRANTY

23. The Plaintiff re-alleges and restates the foregoing allegations.

ANSWER: Teva incorporates by reference paragraphs 1 through 22 of this Answer as if fully set forth at length herein.

24. Defendant Teva Pharmaceuticals expressly warranted to the market, including the Plaintiff, by and through statements made by Defendant or its authorized agents and representatives, orally and in publications, package inserts and other written materials to the health care community, that minocycline was safe, effective, and proper for its intended use.

ANSWER: Teva neither denies nor admits the allegations contained in paragraph 24 of the Amended Complaint to the extent that they state conclusions of law, except admits that Teva complied at all times with applicable statutory and regulatory requirements and obligations with respect to its minocycline product, and respectfully refers the Court to the appropriate product labeling for the terms thereof.

25. In using minocycline, Plaintiff relied on the skill, judgment, representations and express warranties of Defendant Teva Pharmaceuticals. These warranties proved false because the product was not safe and unfit for the uses for which it was intended.

ANSWER: Teva denies each and every allegation contained in paragraph 25 of the Amended Complaint, except admits that Teva's minocycline product was, and is, safe and effective when used in accordance with FDA-mandated and approved product labeling. To the extent paragraph 25 of the Amended Complaint alleges that Plaintiff relied on Teva's skill, judgment, representations and express warranties, Teva denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations.

26. At the time of the express warranties, Defendant Teva Pharmaceuticals had knowledge of the purpose for which minocycline was to be used and warranted it to be safe, effective, and proper for such purpose.

ANSWER: Teva denies each and every allegation contained in paragraph 26 of the Amended Complaint, and specifically avers that Teva complied at all times with applicable statutory and regulatory requirements and obligations with respect to its minocycline product. Teva further admits that its minocycline product was, and is, safe and effective when used in accordance with FDA-mandated and approved product labeling.

27. Defendant Teva Pharmaceuticals knew and had reason to know that minocycline did not conform to these express representations and that minocycline is neither safe or effective and carries the risk of serious side effects.

ANSWER: Teva denies each and every allegation contained in paragraph 27 of the Amended Complaint.

28. Defendant Teva Pharmaceuticals's actions as described were performed willfully, intentionally, and with reckless disregard for the rights of the Plaintiff.

ANSWER: Teva denies each and every allegation contained in paragraph 28 of the Amended Complaint.

29. As a direct and proximate result of Defendant Teva Pharmaceuticals's breach of warranty, Plaintiff was injured and suffered special and compensatory damages to be proven at trial.

ANSWER: Teva denies each and every allegation contained in paragraph 29 of the Amended Complaint.

COUNT III
STRICT LIABILITY

30. Plaintiff re-alleges and restates the foregoing allegations.

ANSWER: Teva incorporates by reference paragraphs 1 through 29 of this Answer as if fully set forth at length herein.

31. Defendant Teva Pharmaceuticals is liable under Section 402A, Restatement (Second) of Torts for strict liability, for the defective design of minocycline. At the time of design, manufacture and sale, safer alternatives existed, including designs other than those actually used, and had such alternatives been selected by Defendant, it would have prevented or significantly reduced the likelihood of Plaintiffs injuries. Such designs were both economically and technically feasible at the time of the products left the possession of the Defendant and had they been used, would not have impaired the ability of the product.

ANSWER: Teva denies each and every allegation contained in paragraph 31 of the Amended Complaint, and respectfully refers all conclusions of law to the Court.

32. Defendant Teva Pharmaceuticals failed to provide adequate warnings and instructions in the marketing of minocycline. Defendant failed to provide adequate instructions for the safe use of minocycline. Defendant's defectively marketed drug was a cause of the Plaintiffs injuries.

ANSWER: Teva denies each and every allegation contained in paragraph 32 of the Amended Complaint, and specifically avers that Teva complied at all times with applicable statutory and regulatory requirements and obligations with respect to its minocycline product, and respectfully refers the Court to the appropriate product labeling for the terms thereof.

33. Defendant Teva Pharmaceuticals is also strictly liable for misrepresenting to Plaintiff that its product was safe and without defect, which statement was false and involved a material fact concerning the character of the product in question, upon which the consumer relied, producing Plaintiff's injuries.

ANSWER: Teva denies each and every allegation contained in paragraph 33 of the Amended Complaint, and specifically denies that Plaintiff suffered any injuries or damages as a result any Teva product.

FIRST AFFIRMATIVE DEFENSE

Plaintiff's Amended Complaint, and each and every allegation therein directed to Teva, fails to state a claim against Teva upon which relief may be granted.

SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims against Teva are barred in whole or in part by the applicable statutes of limitations.

THIRD AFFIRMATIVE DEFENSE

Plaintiff's claims against Teva are barred by laches, waiver, and/or estoppel.

FOURTH AFFIRMATIVE DEFENSE

If Plaintiff did sustain any injury or incur any loss or damage as alleged in the Amended Complaint, the same resulted in whole or in part from an intervening cause and/or causes, and any action on the part of Teva was not the proximate and/or competent producing cause of Plaintiff's alleged injuries.

FIFTH AFFIRMATIVE DEFENSE

If Plaintiff did sustain any injury or incur any loss or damage as alleged in the Amended Complaint, the same were caused in whole or in part by acts or omissions of another or others, over whom Teva neither exercised nor had any right of control, for which Teva is and was not responsible, and whose conduct Teva had no duty or reason to anticipate or control.

SIXTH AFFIRMATIVE DEFENSE

If Plaintiff did sustain any injury or incur any loss or damage as alleged in the Amended Complaint, the same resulted only after Plaintiff knowingly and voluntarily assumed any alleged risk inherent in the use of minocycline.

SEVENTH AFFIRMATIVE DEFENSE

If Plaintiff did sustain any injury or incur any loss or damage as alleged in the Amended Complaint, the same were caused in whole or in part by pre-existing conditions, for which Teva bears no legal responsibility or liability.

EIGHTH AFFIRMATIVE DEFENSE

If Plaintiff did sustain any injury or incur any loss or damage as alleged in the Amended Complaint, the degree of responsibility, negligence, and fault of each person who contributed to said injuries should be determined, and Teva should be held liable only for that proportion of the resulting damage which corresponds to its degree of fault, responsibility, or negligence, if any.

NINTH AFFIRMATIVE DEFENSE

If, in fact, the Amended Complaint is held to contain a claim upon which relief may be granted, then Plaintiff's recovery, if any, should be reduced by the relative amount attributable to Plaintiff or her agents or persons other than Teva.

TENTH AFFIRMATIVE DEFENSE

At all times, minocycline was available to patients only upon the prescription of a licensed physician, and the federal government has preempted the field of law applicable to prescription items and their labeling. Thus, the manufacture, marketing, and labeling of minocycline was controlled by federal law, and Teva was at all times in compliance with applicable federal law with respect thereto; therefore, the Amended Complaint fails to state a claim upon which relief may be granted in that, inter alia, such causes of action, if upheld, would impede, impair, frustrate, or burden the effectiveness of federal law regulating the field of prescription items, would constitute an invalid burden by this Court on interstate commerce, and would, therefore, violate the Supremacy Clause (Article VI, Section 2) and the Commerce Clause (Article I, Section 8) of the United States Constitution. Plaintiff's claims against Teva are barred by the doctrine of Federal Preemption.

ELEVENTH AFFIRMATIVE DEFENSE

Teva discharged its duty to warn by including fair and adequate warnings as to the risks, precautions and potential adverse reactions from using its minocycline product in the product labeling therefor. Accordingly, Teva is not liable to Plaintiff by virtue of the learned intermediary doctrine.

TWELFTH AFFIRMATIVE DEFENSE

At all times, minocycline was available to patients only upon the prescription of a licensed physician. Upon information and belief, Plaintiff's prescribing physicians were aware of all risks that were known or could have been known to be associated with the use of minocycline in accordance with its indications and product use instructions. Accordingly, Plaintiff's claims are barred wholly or in party by the learned intermediary defense.

THIRTEENTH AFFIRMATIVE DEFENSE

Upon information and belief, any injury, loss or damage that Plaintiff may have sustained were caused in whole or in part by Plaintiff's own negligence.

FOURTEENTH AFFIRMATIVE DEFENSE

To the extent the contributory fault on the part of the Plaintiff is more than 50% of the proximate cause of the injury or damage, if any, for which recovery is sought, Plaintiff is barred from recovery.

FIFTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff is found to be not more than 50% at fault, any damages allowed shall be diminished in proportion to the amount of fault attributable to Plaintiff.

SIXTEENTH AFFIRMATIVE DEFENSE

Teva's liability, if any, to Plaintiff for Plaintiff's damages shall not exceed Teva's equitable share determined in accordance with the relative culpability of each person causing or contributing to the total liability for such damages, in accordance with the principles of comparative negligence.

SEVENTEENTH AFFIRMATIVE DEFENSE

If Teva is found liable to Plaintiff, any fault on the part of Teva is less than 25% of the total fault attributable to Plaintiff, the defendants sued by Plaintiff, and any third party. Accordingly, to the extent Teva is liable, it shall only be severally liable for damages other than medical or medically-related expenses.

EIGHTEENTH AFFIRMATIVE DEFENSE

At all times relevant to Plaintiff's claims against Teva, Teva conformed its conduct to the state of medical knowledge, common and accepted procedures in the medical field, professional standards, and the medical and pharmacological state of the art.

NINETEENTH AFFIRMATIVE DEFENSE

Any alleged defect in minocycline could not have been detected or removed by a reasonable use of scientific procedures or techniques.

TWENTIETH AFFIRMATIVE DEFENSE

Plaintiff failed to join and include in this action all identifiable and indispensable parties without whom, in equity and fairness, this action should not proceed.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff failed to state a cause of action against Teva to the extent that Plaintiff is unable to identify Teva as the entity causing the alleged injuries.

TWENTY-SECOND AFFIRMATIVE DEFENSE

To the extent that Plaintiff is unable to identify the manufacturer of the allegedly injury-causing product, the Amended Complaint fails to state a cause of action upon which relief may be granted in that, *inter alia*, Plaintiff has asserted claims for relief which, if upheld, would constitute a taking of private property for a public use without just compensation and such taking would contravene Teva's constitutional rights under both the United States and Illinois State Constitutions.

TWENTY-THIRD AFFIRMATIVE DEFENSE

To the extent that Plaintiff is unable to identify the manufacturer of the allegedly injury-causing product, the Amended Complaint fails to state a cause of action upon which relief may be granted in that, *inter alia*, Plaintiff has asserted claims for relief which, if upheld, would contravene Teva's constitutional rights to substantive and procedural due process of law under both the United States and Illinois State Constitutions.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

To the extent that some or all of Plaintiff's damages will be replaced or indemnified, in whole or in part, from collateral sources, Teva is entitled to a collateral source offset to the extent allowed under Illinois law.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Insofar as any of Plaintiff's claims sound in breach of warranty, Teva made no express or implied warranties to Plaintiff.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

To the extent that Teva made any representations to Plaintiff, any such representations were true and correct.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred by the doctrines described in Sections 6(c) and (d) of the Restatement (Third) of Torts: Products Liability. Reasonable physicians knowing of the reasonably foreseeable risks and therapeutic benefits associated with minocycline would have prescribed and

did prescribe minocycline for classes of patients. In addition, Teva provided prescribing physicians with reasonable instructions or warnings regarding foreseeable risks of harm.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

If Plaintiff did sustain any injury or incur any loss or damage as alleged in the Amended Complaint, the same were caused in whole or in part by Plaintiff's failure to exercise reasonable care and diligence to mitigate her alleged damages.

TWENTY-NINTH AFFIRMATIVE DEFENSE

If Plaintiff did sustain any injury or incur any loss or damage as alleged in the Amended Complaint, the same were caused in whole or in part by misuse, abuse, alteration, and/or failure to properly utilize, maintain, or care for the product by someone other than Teva.

THIRTIETH AFFIRMATIVE DEFENSE

The product made the subject of this action was not in substantially the same condition at the time it was allegedly ingested by Plaintiff and allegedly caused her injuries as when said product allegedly left the control of Teva and entered the stream of commerce.

THIRTY-FIRST AFFIRMATIVE DEFENSE

All products in any way connected with Teva are defect-free and not unreasonably dangerous. Such products fully comply with the products liability standard of Illinois.

THIRTY-SECOND AFFIRMATIVE DEFENSE

Teva reserves the right to assert such other or additional affirmative defenses as may be disclosed in the course of discovery herein.

WHEREFORE, Defendant Teva Pharmaceuticals USA, Inc. respectfully requests that the Amended Complaint be dismissed as to it in all respects, together with such other and further relief as to this Court may seem just and proper.

Dated: March 19, 2008

TEVA PHARMACEUTICALS USA, INC.

/s/ Ameri R. Giannotti

Pamela R. Hanebutt
Ameri R. Giannotti
EIMER STAHL KLEVORN & SOLBERG LLP
224 S. Michigan Avenue
Suite 1100
Chicago, IL 60604
(312) 660-7600 (Telephone)
(312) 692-1718 (Facsimile)
phanebutt@eimerstahl.com
agiannotti@eimerstahl.com

Of Counsel:
Glenn S. Kerner
Yuliya Gertsberg
GOODWIN PROCTER LLP
599 Lexington Avenue
New York, NY 10022
(212) 813-8800 (Telephone)
(212) 355-3333 (Facsimile)
gkerner@goodwinprocter.com
ygertsberg@goodwinprocter.com

Attorneys for Defendant
Teva Pharmaceuticals USA, Inc.

CERTIFICATE OF SERVICE

Ameri R. Giannotti, an attorney, certifies that on March 19, 2008 she electronically filed the foregoing ANSWER OF DEFENDANT TEVA PHARMACEUTICALS USA, INC. TO PLAINTIFF'S FIRST AMENDED COMPLAINT using the ECF system which will automatically send e-mail documentation of such filing to the parties listed below.

/s/ Ameri R. Giannotti
Ameri R. Giannotti

Michael P. Cascino
Vaughan Cascino Law Offices, Ltd.
220 South Ashland Avenue
Chicago, Illinois 60607
(312) 944-0600
(312) 944-1870 (fax)